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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,619	03/01/2004	Gottfried Kellermann	3942	8840

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

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09/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,619	KELLERMANN, GOTTFRIED	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks/arguments and amendments filed on 07/06/2007 are acknowledged.

2. Claims 6, 7 and 12 were amended.

3. Claims 1-13 are included in the prosecution.

Response to Arguments

Rejection of claims 7-11 under 35 USC § 112, first paragraph

4. The rejection of claims 7-11 under 35 USC § 112, first paragraph as not providing enablement for any condition or disorder is moot in light of applicant's amendment of claim 7 to recite that the subject being treated has neurotransmitter over-stimulation. The rejection of 2/6/07 is withdrawn.

Rejection of claim 6 under 35 USC § 112, second paragraph

5. The rejection of claim 6 under 35 USC § 112, second paragraph as being indefinite because the claim includes "an additional therapeutic moiety" is moot in light of applicant's amendment of claim 6 to clarify that the additional therapeutic moiety is an additional compound. The rejection of 2/6/07 is withdrawn.

Rejection of claims 7-11 under 35 USC § 112, second paragraph

6. The rejection of claims 7-11 under 35 USC § 112, second paragraph as being incomplete for omitting essential elements because the conditions to be treated by the claimed method are not disclosed in the claims is moot in light of applicant's

amendment of claim 7 to recite that the subject being treated has neurotransmitter over-stimulation. The rejection of 2/6/07 is withdrawn.

Rejection of claims 1-6 and 7-11 under 35 USC § 103(a)

7. Applicant's arguments with respect to the rejection of claims 1-6 and 7-11 under 35 USC § 103(a) as being unpatentable over Keller et al. (US 5,891,465) in view of Ueda et al. (US 6,589,566) have been fully considered but are not persuasive.

Applicant argues that Keller does not teach delivery of theanine or 5-hydroxytryptophan, a liposomal composition comprising theanine, a liposomal composition comprising 5-hydroxytryptophan (5-HTP), or the administration of a composition comprising theanine to treat a subject having neurotransmitter over-stimulation. Applicant argues that Ueda does not teach liposomal compositions, that the teachings of Keller and Ueda do not suggest the applicant's invention, and that the differences between applicant's claimed invention and the teachings of the cited references would be unobvious to one skilled in the art.

Although Keller does not expressly teach the use of theanine or 5-HTP, it does teach compositions and methods of administering drugs that are encapsulated in lipid vesicles. The deficiency of Keller in terms of a composition comprising theanine is cured by the Ueda reference which teaches a composition comprising theanine that suppresses and ameliorates symptoms including "anxiogenic symptoms" that are generally associated with neurotransmitter over-stimulation. One skilled in the art would be motivated to combine the liposomal encapsulated composition of Keller with the teaching by Ueda that theanine is used to treat symptoms of neurotransmitter over-

stimulation because of the advantage of sublingual absorption of the liposomal encapsulated spray taught by Keller. The combination of theanine and 5-HTP would have been obvious given the advantage of using these components for the treatment of symptoms caused by neurotransmitter over-stimulation.

Therefore, the rejection of 2/6/07 is maintained.

Rejection of claims 7-13 under 35 USC § 103(a)

8. Applicant's arguments with respect to the rejection of claims 7-13 under 35 USC § 103(a) as being unpatentable over Blum (US 6,132,724) in view of Keller et al. (US 5,891,465) have been fully considered but are not persuasive.

Applicant argues that Blum does not include theanine and 5-HTP in a liposomal encapsulated composition and there is no suggestion to combine the Blum reference with the Keller reference. Applicant argues that the combination of Blum and Keller is the result of improper hindsight reconstruction.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Blum teaches a composition that includes 5-HTP and theanine and that these components promote restoration of normal neurotransmitter functions. Therefore, one skilled in the art would

know that the combination of 5-HTP and theanine is useful for treating subjects having neurotransmitter over-stimulation. The combination with the Keller reference would have been obvious in light of the advantage of sublingual absorption of the liposomal encapsulated spray.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore, the rejection of 2/6/07 is maintained.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-6, and 7-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (US 5,891,465) in view of Ueda et al. (US 6,589,566).

The claimed invention is a composition of a liposomal encapsulated solution containing L-theanine and 5-Hydroxytryptophan. The method of administering the composition is by a spray bottle. Claims 1-6 are drawn to a composition of a liposomal encapsulated solution containing L-theanine and 5-Hydroxytryptophan (5-HTP). Claims 7-11 are drawn to a method of treating a subject using the said composition.

Keller et al. teach compositions and methods of administering drugs or nutritional supplements that are encapsulated in lipid vesicles. The methods of administration include a liquid droplet spray (Abstract). The method of administration by the spray allows the nutritional supplements to be absorbed sublingually (Col 1, lines 10-16). The advantage of sublingual administration is that it "avoids the first pass effect" (Col 2, lines 42-44), provides "increases in the bioavailability and improved therapeutic response..." (Col 3, lines 31-35), and could decrease "the amount of agent that is administered" (Col 4, lines 15-21). "Any form of nutritional supplement that is capable of being entrapped in or bound to the lipid vesicle, can be included..." in the composition (Col 5, lines 3-5). Keller et al. do not teach the use of theanine or 5-HTP in the liposomal encapsulations.

Ueda et al. in US 6,589,566, teach a composition comprising theanine that suppresses and ameliorates symptoms including "anxiogenic symptoms" that are generally associated with neurotransmitter over-stimulation (Col 1, lines 13-17). It is taught that L-theanine is the preferred form of theanine "because it is approved as a food additive, and it is economically utilizable" (Col 3, lines 6-8). The theanine containing composition "may be prepared as ... solutions ..." (Col 6, lines 55-59).

A person with ordinary skill in the art at the time the invention was made would have been able to use the liposomal encapsulated nutritional supplement spray of Keller et al. with the theanine containing solution taught by Ueda et al. given the advantages of sublingual absorption of the liposomal encapsulated spray. One would further have been motivated to use L-theanine and 5-HTP in the liposomal encapsulated composition given the advantage of using these components for the treatment of symptoms caused by neurotransmitter over-stimulation (such as headaches, ADHD, etc.).

As to claims 4 and 5, a person with ordinary skill in the art could, without absent evidence to the contrary, arrive at the optimal concentration range of theanine in the liposomal encapsulated spray solution.

Claim 6 includes "an additional therapeutic moiety". As mentioned above, Keller et al. teach that any nutritional supplement that can be bound in a lipid vesicle can be included. Therefore, to include an additional therapeutic moiety, which can be bound in a liposome, would be obvious to one with ordinary skill in the art.

Claims 7-11 are intrinsically met because the composition of Keller et al. is made to be administered to a subject. Therefore, treatment of a subject with nutritional supplements is inherently met.

11. Claims 7-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Blum (US 6,132,724) in view of Keller et al. (US 5,891,465).

Claims 7-11 are drawn to a method of treating a subject and claims 12-13 are drawn to a method of treating a subject with neurotransmitter over-stimulation

symptoms such as headaches or attention deficit hyperactivity disorder, by using a liposomal encapsulated solution containing L-theanine and 5-HTP. The method of administering the composition is by a spray bottle.

Blum teaches a method of treating a subject for behaviors that include "attention deficit hyperactivity disorder" (Col 22, line 36-38) by using a composition that includes the neurotransmitter precursor 5-Hydroxytryptophan and Theanine (Col 75, Table 20). "These components promote restoration of normal neurotransmitter functions ..." (Abstract). Blum does not teach a liposomal encapsulation.

It would have been obvious to make a liposomal encapsulation when Blum is taken in view of Keller et al. because of the teaching of Keller et al. regarding the liposomal encapsulation of nutritional supplements (described in detail in the 103(a) rejection above). A pump spray administration device for the lipid-encapsulated agents is also taught (Col 5, lines 23-27).

A person with ordinary skill in the art at the time the invention was made would have been motivated to combine the method of treatment of restoring normal neurotransmitter functions by using a composition with theanine and 5-HTP taught by Blum with the liposomal encapsulated nutritional supplement spray of Keller et al. given the advantages of sublingual absorption of the liposomal encapsulated spray.

As to claims 9 and 10, a person with ordinary skill in the art could, without absent evidence to the contrary, arrive at the optimal concentration range of theanine in the liposomal encapsulated spray solution via routine practice of optimization of drug dosage.

Conclusion

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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